Item 9. 35 U.S.C. §103(a)

Claims 73-104 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Edwards et al (July 1998, *Plant Physiology* 117: 1015-1022) in view of Harada et al (U.S. Patent 6,235,975 B1, filed 24 June 1998).

Applicants respectfully traverse the rejection and its supporting remarks.

Firstly, Applicants conceived of the present invention prior to the publication of the Edwards reference, and worked diligently to reduce the claimed invention to practice. In priority application 60/125,814 on 03/23/99, Applicants disclosed transgenic plants comprising the same sequence that Edwards taught, and Applicants reduced the invention to practice before one year after the Edwards publication had elapsed. Please see the attached declaration under 37 CFR 1.131 of Dr. Luc Adam, showing that Applicants designed primers for a G482-overexpressing plant at least as early as December 3, 1997, and continued to design primers for this sequence up to and after July 10, 1998, the earliest date the Edward publication may have been available to the public (this date is indicated in the attached email from Ms. Nancy Winchester, Director of Publications, of the *American Society of Plant Biologists*, publisher of *Plant Physiology;* Ms. Winchester has consented to the use of this email for this and related responses). The file creation dates of two of the files referred to in the Adam declaration can be seen in the attached file "G481G482ArchivalFiles.pdf". The file "12000 annotated ESTs.xls" was created on April 26, 1998, and the file "la.xls" was created on July 8, 1998. Thus, Applicants conceived of the invention prior to the effective date of the reference, and said conception was coupled with due diligence from prior to said date to the filing of the 60/125,814 application on 03/23/99.

Secondly, the Examiner has asserted as the reason that one of skill in the art would express the AtHAP3b CAAT-box transcription factor in a plant is that "Edwards teaches that the AtHAP3b CAAT-box transcription factor appears to be expressed in relation to osmotic stress and hence, would have motivated one of skill in the art to produce a transgenic plant." See page 17, lines 11-13, of the Office Action dated 4/14/2008. However, section 2107.01(I)(B) of the MPEP states that:

> **On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":**
>
> **(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;**
>
> **(B) A method of treating an unspecified disease or condition;**
>
> **(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;**
>
> **(D) A method of making a material that itself has no specific, substantial, and credible utility; and**
>
> **(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.**

Thus, the Examiner's asserted reason of expressing the polypeptide to determine whether the AtHAP3b CAAT-box transcription factor has any real world effect upon a plant's response to salt or osmotic stress seems to fall under category (A) wherein a material is subject to further research to demonstrate a "real world" utility. Without such a real world utility, one of skill in the art would not be motivated to actually express the protein in a plant. This is clearly discussed in Section 2144 of the MPEP:

> **If the prior art does not teach any specific or significant utility for the disclosed compounds, then the prior art is not sufficient to render structurally similar claims *prima facie* obvious because there is no motivation for one of ordinary skill in the art to make the reference compounds, much less any structurally related compounds. In re Stemniski, 444 F.2d 581, 170 USPQ 343 (CCPA 1971).**

Thus, *In re Stemniski* touches upon a closely analogous situation to that presented here. The Edwards reference teaches the AtHAP3b gene appears to be expressed in relation to osmotic stress, but provides no evidence of whether expression of AtHAP3b would have any effect upon the osmotic stress response of a plant. Therefore, the only utility suggested by the Examiner is not a real world utility and therefore not a "specific or significant" utility. By contrast, the inventors have identified a substantial and significant utility, for example, improving the salt tolerance of the transgenic plant. Just as in *In re Stemniski* where one of skill in the art would not have a motivation to modify the disclosed compounds since they had no specific or significant utility, Edwards et al. cannot render obvious the modification of the AtHAP3b CAAT-box transcription factor gene by transgenically expressing it in a plant since Edwards et al. similarly fail to teach a "specific or significant" utility.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(b) be withdrawn.

Items 11. Provisional obviousness type double patenting

Applicants note that the MPEP indicates that: "The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which *would have been obvious* to those of ordinary skill in the art *at the time the invention was made*, taking into account the skill in the art and prior art other than the invention claimed in the issued patent" (*emphasis* added). The present application, being the earlier filed application with the earlier priority date, would not have been obvious to one of ordinary skill in light of U.S. patent application 11/069,255, since the latter did not yet exist at the time the present invention was made.

The MPEP also indicates that: "If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and

permit the earlier-filed application to issue as a patent without a terminal disclaimer." (MPEP 804(I)(B)(1)).

In light of the present amendments and arguments, Applicants believe that all other rejections may be presently overcome, and thus respectfully request that this ground of rejection be held in abeyance until patentable subject matter is defined for the present application.

CONCLUSION

Applicants believe that no additional fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Mendel Biotechnology, Inc. Deposit Account No. **50-1025.**

Respectfully submitted,
MENDEL BIOTECHNOLOGY, INC.

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JML/jml
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Attachments:

- File: "2_RCE_sb0030.pdf"; Request for Continued Examination (1 page)
- File: "3_MBI-0022CIP_LAdam_131.pdf"; Declaration under 37 CFR 1.131 of Dr. Luc Adam (5 pages)
- file: "4_60125814_G482.pdf"; Excerpted pages from priority application 60/125,814 (4 pages)
- File: "5_Winchester_Email.pdf": Email from Ms. Nancy Winchester, Director of Publications, of *American Society of Plant Biologists* (1 page)
- File "6_ArchivalFiles.pdf" (1 page)